DIA

11th European Forum for Qualified Person for Pharmacovigilance (QPPV)

4-5 October 2017 | The Crystal, London, UK

PROGRAMME CO-CHAIRS

Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

Peter De Veene, Head Global Drug Safety & QPPV, Grünenthal, Germany

PROGRAMME COMMITTEE

Barbara De Bernardi, EU QPPV Deputy, Pfizer Italia S.r.l., Italy

Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd, UK

Doris Stenver, Chief Medical Officer, Danish Medicines Agency, Denmark

Elspeth McIntosh, Director, Castle Pharmacovigilance Ltd., UK

Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd., UK

Vicki Edwards, EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, UK

Winrich Rauschning, QPPV, BioLitec Pharma, Germany

CONTINUING EDUCATION

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with 15 credits for pharmaceutical medicine.

OVERVIEW

This is the only forum designed for QPPVs by QPPVs, now in its 11th year and ever growing. This year's objectives, as shown below, build on past successes and have been shaped by valuable feedback provided by participants of the past ten meetings.

Over time, one of the key successes of the Forum has been the ability to secure continuing support and involvement of key regulators. Sessions have been open and interactive with attendees appreciating opportunities to raise challenging issues in an informal environment. This 11th QPPV Forum aims to continue to attract such key speakers and encourage open debate.

OBJECTIVES

- Hear the latest updates and hot topics relating to the role of the QPPV
- Explore long term PV visions, future directions of the 'PV world', and potential impact on the role of QPPV
- Network with colleagues and meet regulators
- Learn from and share experience and ideas with like-minded QPPVs in a neutral environment
- Take away practical hints and tips
- Better understand regulatory and inspectorate expectations of the QPPV
- Identify the expanded expectations of the role in the context of the new regulatory framework and transparency initiatives
- Examine current areas of real challenges

WHO WILL ATTEND?

- QPPVs
- Deputy QPPVs
- Pharmacovigilance Consultant
- Director Pharmacovigilance Oversight and Standards
- Drug Safety Manager
- Audits
- Drug Safety Leader
- Medical and Regulatory Affairs Experts
- Pharmacists
- Drug Safety Scientists

FINAL PROGRAMME

11th European Forum for QPPVs

DAY ONE I WEDNESDAY, 4 October

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

KEY NOTES

Session Chair:
Michael Richardson, International Head of GPV&E and EU QPPV, Bristol-Myers Squibb Pharmaceuticals Ltd., UK

The environment in which the pharmaceutical industry lives has seen dramatic changes in the past decade driven by changing legislation, heightened patient expectations on efficacy and safety and funding and access of medicines controlled by payers. This changed milieu has necessitated a confluence of pharmacovigilance, development and commercialisation of medicines to engage earlier and more transparently with regulators and payers:

This session will ask key regulators and Industry the following questions:

- Have the deliverables of transparency, simplification and enhanced evaluation of benefit risk been achieved?
- Have regulators and Industry in particular the QPPV better oversight and insight to the use of medicines
- Have Patients and Healthcare providers received better and clearer information on the products they use?
- In the changed global environment have Industry achieved optimal organisational and functional models to continue successful delivery of new medicines and ensure safe and appropriate use and access of these
- Does Senior leadership in Industry support the role of the QPPV and the principle of single point oversight of the safety system?

June Raine, Director - VRMM & Chairman of the PRAC, MHRA, United Kingdom

Saad Shakir, Director, Drug Safety Research Unit, United Kingdom

10:30 COFFEE BREAK

11:00 SESSION 2

HOT TOPICS FOR QPPV OVERSIGHT

Session Chair: **Vicki Edwards**, EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, United Kingdom

This will be year three for this very popular session. Typically the session invites speakers who are leading discussions between industry trade associations and Regulatory Authorities on the key issues of the moment. The session provides insight into what are the hot topics under discussion, what progress has been made and what are the next steps. The session is of value to participants from both large and small companies alike as there is limited attendance possible at the public meetings with EMA so this is a fantastic opportunity to hear about these topics from individuals who are directly involved. The session consists of a series of short, concise presentations that cover the key messages. This session is always a crowd pleaser!

Clinical Trials regulation and RSI
Esteban Herrero-Martinez, Director Regulatory Policy and Intelligence, Abbvie Ltd, United Kingdom

Module IX – Signal Management
Sue Rees, EU QPPV, Executive Director, Global Patient Safety, Amgen Ltd, United Kingdom

Module VI updates
Peter De Veene, Head Global Drug Safety & QPPV, Grünenthal, Germany

New Paediatric Guideline
Guy Demol, EU QPPV, MSD, Belgium

12:30 LUNCH

14:00 SESSION 3

HOT TOPICS – A REGULATORS' PERSPECTIVE

Session Chair:
Doris Stenver, Chief Medical Officer, Danish Medicines Agency, Denmark

The activities in the Pharmacovigilance Risk Assessment Committee (PRAC) covers a wide range of procedures, and the level of experience has reached a high level of matureness more than 5 years after the 2012 EU pharmacovigilance legislation came into force. For the QPPV it is important to keep abreast with the PRAC activities, and the current session will provide valuable insight into the functioning of the PRAC. Which are the current hot topics the committee is dealing with? Who are the most important stakeholders and how does the PRAC cooperate with them? Answers to these and many more questions will be provided in this session.

PRAC updates and 2018 workplan
Doris Stenver, Chief Medical Officer, Danish Medicines Agency, Denmark

Feedback on PRAC´s first public hearing and highlights on signal management
Sabine Straus, Head of Pharmacovigilance, Medicines Evaluation Board (MEB), The Netherlands

The RMP in the life cycle of the product – originator/generic/biosimilar
Emil Andrei Cochino, Scientific Officer, Anti-infectives and Vaccines, SRM Department, European Medicines Agency (EMA), European Union
Nuria Semis-Costa, European Medicines Agency (EMA), European Union

15:30 COFFEE BREAK

16:00 SESSION 4

BREXIT: DISCUSSION ON THE POTENTIAL CONSEQUENCES ON PHARMACOVIGILANCE

Session Chair: **Peter De Veene**, Head Global Drug Safety & QPPV, Grünenthal, Germany

On 29 March 2017, the United Kingdom (UK) notified the European Council of its intention to withdraw from the European Union (EU), a process known as 'Brexit'. In this session, we will explore the implications of this Brexit on the pharmaceutical industry and in particular the consequences for the pharmacovigilance area, both in terms of regulatory system as well as the impact on companies. We will hear both from the regulators and industry how these changes might impact us and how we can prepare to minimize the impact after the UK leaves the EU on 30 March 2019.

Mick Foy – Group Manager, Vigilance Intelligence and Research Group Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Agnes Saint-Raymond, Head of Portfolio Board, Head of International Affairs, European Medicines Agency, European Union

Q&A:
Vicki Edwards, EU QPPV and Head of Affiliate Vigilance Excellence, AbbVie, United Kingdom

To provide an update on EFPIA activities with respect to Brexit and to focus in particular on collaboration between ABPI and EFPIA PV Expert Group in ensuring agreed recommended PV position is heard by government.

17:30 END OF DAY ONE

18:30 NETWORKING DINNER

11th European Forum for QPPVs

DAY TWO | THURSDAY, 5 OCTOBER

09:00 SESSION 5

INSIGHTS ON INSPECTIONS, AUDITS AND QUALITY MANAGEMENT

Session Chair:

Brian Edwards, Principal Consultant, Pharmacovigilance and Drug Safety, NDA Regulatory Science Ltd., UK

The QPPV is important in directing the interpretation of pharmacovigilance legislation and guidance. QPPVs have considerable flexibility but the basis of the decision must be transparent and properly documented. QPPVs must be able to explain the rationale of why a process is set up in a certain way or whether further changes are required to produce a compliant process. Challenges for quality include obtaining cross-functional ownership of issues and ensuring that all root causes remained addressed by corrective and preventive action plans. This session will explore the different experiences of the MAHs systems that both inspectors and auditors have recently had, how their activities have been supported by the QPPV and how they might expect the MAH to approach human error, communications between departments and other options, apart from audit, that the MAH might use to assess quality.

Speakers:

Kiernan Trevett, Senior Pharmacovigilance Inspector MHRA, United Kingdom

Leen Verbert, PV QA & Training Director, GlaxoSmithKline Biologicals, Belgium

Magnus Ysander, EU QPPV & Head Pharmacovigilance Excellence AstraZeneca AB, Sweden

10:30 COFFEE BREAK

11:00 SESSION 6

EU QPPV OVERSIGHT OUTSIDE EU & ´QPPV REQUIREMENTS OUTSIDE EU´: HOW TO MARRY THESE UP

Session Chair:

Barbara De Bernardi, EU QPPV Deputy, Pfizer Italia S.r.l., Italy

Pharmacovigilance has evolved significantly over the past ten years in the EU, where the EU QPPV has a key role in the oversight of PV system for all medicinal products for which the company holds marketing authorisations.

The adoption of principles similar to those in the EU PV legislation is increasing in a significant number of ex-EU countries and regions (e.g. Arab league, EAEU league, Ukraine, Israel, Turkey, Cambodia, Malaysia, Ghana, Nigeria, Kenya, etc). The availability of a Pharmacovigilance Responsible Person is now mandatory in many of them in order to ensure PV system compliance.

This increasing complexity of regulatory requirements across the regions needs intense interactions between EUQPPV, ex-EUQPPVs and Local PV contacts.
Therefore, should the EUQPPV role be « globalized » to play the additional business critical role of "company PV policy holder"?
This session will provide updates on current regulatory and industry scenarios.

Pharmacovigilance System Master File
Willemijn Van Der Spuij, Director International Operations & PV Excellence, Bristol-Myers Squibb, Switzerland

Pharmacovigilance in the Rest of the World
Esteban Herrero-Martinez, Director Regulatory Policy and Intelligence, Abbvie Ltd, United Kingdom

12:30 LUNCH

13:30 SESSION 7

QPPV OVERSIGHT – CHANGE MANAGEMENT IN LINE WITH PHARMACOVIGILANCE SYSTEM UPDATES

Session Chair:

Margaret Walters, Director & Deputy EU QPPV, Merck Sharp & Dohme Ltd, UK

In November this year the EMA will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in line with the revised EU Pharmacovigilance legislation. This session will provide updates from several key EMA implementation leads together with an example of an MAHs planning for change. This will be followed by a panel discussion with key EMA speakers towards better enabling effective QPPV oversight of timely and effective internal implementation. Specific topics will include challenges for reporting (including ICSR downloads), processes for MAH signaling in EV and related access policy/data privacy questions.

Speakers:

Francois Domergue, EV Auditable Requirement Project Manager, Business Data and Analytics Department, European Medicines Agency, European Union

Nick Halsey, Scientific Administrator, Data Collection and Management, European Medicines Agency, European Union

16:00 END OF THE CONFERENCE

Conference Venue

The Crystal
One Siemens Brothers Way
Royal Victoria Docks, London E16 1GB
Tel.: +44 (0)207 055 6400 Email: info@thecrystal.org

Dinner Location

The Networking (Buffet) Dinner will start at 18:30h at the:
Crowne Plaza London - Docklands
Royal Victoria Dock
Western Gateway
London, E16 1AL
T: + 44-20-70552000
Dress code: business casual

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As a benefit of your registration, presentations are made available on the DIA website.
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No paper copies of the presentations will be provided.

NOTE: If a presentation is not available, the speaker either did not agree to publish it or did not provide us with their presentation. Updated versions of the slides will be made available shortly after the conference.

Evaluation

Your comments and views on the content and organisation of the event are highly valued. The evaluation form will be available online:
https://www.surveymonkey.de/r/YXGQ25Q

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